Detailed Action

This Office Action is in response to the Applicant's reply received 8/15/11. Claims 1, 7-12, 19-28, 30-37 are pending. Claims 30-35 are withdrawn. Claims 1-7, 12, 19-28, 36 and 37 are considered on the merits.

Response to Amendments

In the response submitted by the Applicant the following 35 U.S.C § 102 rejections are withdrawn:

- Claims 1, 7, 19-23 and 36 as being anticipated by Trau et al. in light of support by Merriam-Webster.com

The following 35 U.S.C § 103 (a) rejections are withdrawn:

- Claims 1, 7-12, 19-23, 28 and 36 as being unpatentable over Trau et al., in view of Zaitsev et al. in further view of Vriezema et al.
- Claims 1, 7, 19-23, 26, 36 and 37 as being unpatentable over Trau et al. in view of Hodak et al.

The Applicant's amendments limiting the anode and cathode are compartmentalized necessitated the above withdrawal. Also the 35 U.S.C § 112 rejection of claim 26 is withdrawn in light of the Applicant's amendment removing "such as".

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 12, 19-28, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new limitation that "disposed within said anode compartment, within said cathode compartment, or between said anode compartment and said cathode compartment" is confusing since it is written in the alternative. This creates the scenario where the oxidase is only in contact with the cathode, rather than the anode. However this is confusing since in a typical electrochemical cell, electrons are collected at the anode and then passed in a current to the cathode. Since the oxidase in the particles is what is generating the electrons via the oxidation of its substrate, then it must be disposed with the anode or the electrons cannot be collected from the enzyme so that the current of the battery flows.

In the interest of compact prosecution, the claims will read that the oxidase encapsulated particle is at least disposed with the anode in the battery.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, 19-23, 26, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trau et al. (Biosensors and Bioelectronics, Available online 5/14/03) in view of Ritts et al. (WO 2003/050896, published June 2003, in IDS 12/19/07) in light of support from Merriam-Webster.com ("battery" definition #4 and "electrolyte").

These claims are to a battery comprising:

- An anode compartment including an anode;
- A cathode compartment including a cathode;
- An electrolyte suspension comprising plurality of hollow particles entrapping an oxidase enzyme, specifically **glucose oxidase (GOX)**;
- These enzyme entrapped particles comprise an outer shell that is electrically conductive and permeable to the enzyme substrate.

These claims have a series of intended uses as follows:

- The battery is for use in combination with a microchip;
- The electrolyte suspension can be used to generate a current of electrons.

These intended uses and do not impart a structural relationship, such as an additional component, to this composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by their components, these intended uses are afforded little patentable weight.

Claim 1 contains product by process language that includes the step of entrapping the oxidase enzyme in the hollow particle. However once the enzyme is in the hollow particle, it is no longer hollow. Therefore since the patentability depends on the final structure of the battery, these product by process limitations are afforded little

patentable weight and an oxidase entrapped in a particle will read on these limitations (M.P.E.P 2113).

Also the term "battery" is not explicitly defined in the specification. While the Applicant appears to mean "battery" as the galvanic cell of figure 1, the common use of the term "battery" is far broader. Merriam Webster online defines battery in the electrical sense as "a combination of apparatus for producing a single electrical effect" or "a single cell that furnishes electric current". Therefore in the broadest but reasonable terms a battery is any apparatus or composition that generates an electric current or produces a single electrical effect. Claims reading on such an apparatus or composition will read on these claims.

Trau et al. teach **glucose oxidase** (**GOX**) entrapped in particles with outer shells comprising polyelectrolytes (Fig 1, and Fig 2B) such as **polyallylamine-HCl (PAH)**, **poly-(sodium-4-styrenesulfonate) (PSS)** and **polyacrylic acid (PAA)** (pg 1493, Section 2.1). These particles are embedded in an electrically conductive matrix such as a platinum/carbon electrode or a gel-like membrane (Figs 2B and C and Fig 5). Trau et al. teach that these particles generate a current upon addition of glucose (Fig 7) and thus meet the broad definition of battery. Trau et al. teach that their GOX encapsulated and embedded on the electrode (Fig 2C) has enhanced stability compared to simply immobilizing the enzyme directly to the electrode (Trau, pg 1493, col 1, middle).

Since these materials are classified as electrolytes they are inherently electrically conductive as supported by Merriam Webster Online ("electrolyte", Definition 1). Furthermore the outer shells of these particles made of these polyelectrolytes inherently

have conductivity and substrate permeability as indicated by the current generated when glucose is added to these hollow particles entrapping GOX (Fig 7). If these hollow particles were not inherently permeable to glucose than no current would be generated by the GOX for lack of substrate. If these hollow particles were not electrically conductive than they would insulate the GOX and prevent current flow. Both of these scenarios are unlikely given the substantial current flow over the control shown in Fig 7 that is a direct result of glucose addition.

What Trau et al. does not teach is the configuration of the battery that comprises compartments for the anode and cathode. Regardless this would have been obvious to one of ordinary skill in the art from the teachings of Ritts et al.

Ritts et al. teach that typical configurations for biofuel cells and batteries that use a variety of oxidases including GOX (Ritts, pg 24, line 23) have both the anode and cathode compartmentalized via a membrane (Ritts, Fig 3B-3E). However Ritts et al. also teach that their anode can be impregnated with enzyme (pg 51, lines 18-21) with electron mediators such as ferrocene or viologens (Ritts, pg 51, lines 1-15). Since True et al. already taught that their encapsulated and immobilized enzymes are more stable than a directly immobilized enzyme it would have been obvious for one of ordinary skill in the art to substitute the GOX encapsulated electrode of Trau et al. with the electron mediators into the battery of Ritts et al.

Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 8-12 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trau et al. and Ritts et al. as applied to claims 1, 7, 19-23, 26, 36 and 37 above, and further in view of Zaitsev et al. (Colloids and Surfaces A, available online May 2003) in further view of Vriezema et al. (Angew. Chem. Int. Ed. Available online, 2003).

While Trau et al. and Ritts et al. teach encapsulating GOX in the polyelectrolyte PSS, they do not teach is that the GOX is entrapped in hollow particles made from PS-PIAT. However this would have been obvious given the combined teachings of Zaitsev et al. and Vriezema et al.

Like Trau et al., Zaitsev et al. teach that hollow particles made of the same polyelectrolyte, PSS (Zaitsev, sec 2.1), but instead of GOX, Zaitsev et al. encapsulate the enzyme lipase while retaining its activity (Zaitsev, Abstract). Therefore it would have been obvious to one of ordinary skill in the art that both GOX and lipase are successfully encapsulated in electrically conductive hollow spheres under the same conditions. What Trau et al. and Zaitsev et al. do not teach is that the material to encapsulate is PS-PIAT with polythiophene sidechains. This is taught by Vriezema et al., who teach that electrically conductive hollow particles made from the block copolymer PS-PIAT (Fig 1 and 2) that encapsulates the lipase (pg 775, col 1) and are approximately 100 nm in diameter so read on the limitation of a nano-battery. Vriezema et al. teaches that the PS-PIAT particles are polymerized to the thiophene side-groups via the chemical oxidant BRP (pg 774, col 1). Vriezema et al. teaches that their encapsulation method enhances enzyme stability (Vriezema, pg 775, col 2).

It would have been obvious to one of ordinary skill in the art to replace the polyelectrolyte polymers of Trau et al. with the PS-PIAT of Vriezema et al. in the encapsulation of GOX. This is because Zaitsev et al. teaches that lipase and GOX are successfully encapsulated under the same conditions, therefore one of ordinary skill in the art would predict that since lipase was successfully encapsulated in PS-PIAT, then likewise so too would GOX. Furthermore both the polyelectrolyte capsule and the PS-PIAT capsule are electrically conductive and allow substrate to permeate through the shell (Zaitsev, pg 775, col 2). Both teach that their encapsulation methods enhance enzyme stability. Also both Trau et al. and Vriezema et al. refer to their enzyme entrapping capsules as "reactors" (Trau, Abstract; Vriezema, pg 775, col 1 and 2), therefore establishing that both are known for the same purpose. Therefor one of ordinary skill in the art would recognize that it would have been obvious to substitute the polyelectrolyte capsules in the battery of Trau et al. with the conductive PS-PAIT capsules of Vriezema et al. since they both are known to encapsulate enzymes, enhance enzyme stability and are conductive, so would have been predicted by one of ordinary skill in the art to function in the same matter since they have similar physical properties (KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007) pg 14) .

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments against combining Trau et al. with Vriezema et al. and Zaitsev et al.

The Applicant has argued that Trau et al. does not teach "hollow particles having an oxidase entrapped therein, such as are set forth in claim 1". This argument is not persuasive since it is semantically a contradiction. A hollow particle is no longer a hollow once it has an item trapped inside. Therefore claim 1 has set forth a product by process limitation that has hollow particles encapsulating enzymes. However Product by Process claims are not limited by the manipulations of the recited steps, only the structure implied by the steps (M.P.E.P. § 2113). Therefore the final structure is a particle that is entrapping an enzyme, which is what is broadly disclosed in Trau et al.

Applicants argue that Vriezema et al. and Zaitsev et al. individually do not teach certain limitations. However as the Examiner laid out in the previous office action and the new rejection above, the claimed invention becomes obvious when the references are considered together as a whole rather than each alone. M.P.E.P. § 2145 IV is clear that "One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references".

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06).

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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